

PATENT COOPERATION TREATY

Translation

From the
INTERNATIONAL SEARCHING AUTHORITY

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

To:

321

Date of mailing
(day/month/year)

Applicant's or agent's file reference

040902WO/SG

FOR FURTHER ACTION

See paragraph 2 below

International application No.

PCT/EP2004/008321

International filing date (day/month/year)

24.07.2004

Priority date (day/month/year)

08.08.2003

International Patent Classification (IPC) or both national classification and IPC

Applicant

IMPELLA CARDIOSYSTEMS AG

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☒ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☒ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/EP

Authorized officer

Facsimile No.

Telephone No.

WRITTEN OPINION OF THE
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International application No.

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Box No. I

Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
☐ This opinion has been established on the basis of a translation from the original language into the following language
_____, which is the language of a translation furnished for the purposes of international search (under Rule 12.3 and 23.1(b)).
2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material
☐ a sequence listing
☐ table(s) related to the sequence listing
 - b. format of material
☐ in written format
☐ in computer readable form
 - c. time of filing/furnishing
☐ contained in the international application as filed.
☐ filed together with the international application in computer readable form.
☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

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Box No. II

Priority

1. ☒ The following document has not yet been furnished:

☒ copy of the earlier application whose priority has been claimed (Rule 43bis.1 and 66.7(a)).

☐ translation of the earlier application whose priority has been claimed (Rule 43bis.1 and 66.7(b)).

Consequently it has not been possible to consider the validity of the priority claim. This opinion has nevertheless been established on the assumption that the relevant date in the claimed priority date.

2. ☐ This opinion has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid (Rules 43bis.1 and 64.1). Thus for the purposes of this opinion, the international filing date indicated above is considered to be the relevant date.

3. Additional observations, if necessary:

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International application No.

PCT/EP2004/008321

**Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability:
citations and explanations supporting such statement**

1. Statement

Novelty (N)	Claims	<u>4, 5, 8</u>	YES
	Claims	<u>1-3, 6, 7, 9</u>	NO
Inventive step (IS)	Claims	<u>4</u>	YES
	Claims	<u>1-3, 5-9</u>	NO
Industrial applicability (IA)	Claims	<u>1-9</u>	YES
	Claims	<u></u>	NO

2. Citations and explanations:

1 This opinion makes reference to the following document:
D1: US 5 061 256 A (WAMPLER RICHARD K) 29 October 1991 (1991-10-29)

2 INDEPENDENT CLAIM 1

2.1 The present application does not meet the requirements of PCT Article 33(1), because the subject matter of claim 1 is not novel within the meaning of PCT Article 33(2). The wording of claim 1 is very broad and vague, as a consequence of which document D1 falls under the scope for which protection is sought.

Document D1 (column 3, line 51 to column 4, line 9; column 4, lines 50-52; figures 2, 6) discloses (the references between parentheses refer to this document):

Intracardiac pump device for percutaneous insertion, with a pump (10) whose proximal end is connected to a catheter (14) and whose distal suction end is

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Box No. V

Reasoned statement under Rule 43bis1(a)(i) with regard to novelty, inventive step or industrial applicability;
citations and explanations supporting such statement

connected to a cannula (16) which, in the area away from the pump, has inlet openings (two openings 48 and circular opening of the cannula at the proximal end of the oblique opening 46),
a flexible extension piece (distal part of 38 on that side of the circular opening of the cannula) being provided on the cannula in the area in the distal direction from the inlet openings.

3 DEPENDENT CLAIMS 2, 3, 5-9

Claims 2, 3, 5-9 do not contain any features which, in combination with the features of any claim to which they refer back, meet the PCT requirements for novelty and inventive step. D1 also discloses all the technical features of claims 2, 3, 6, 7 and 9 (explanation of claims 3 and 9: claim 1 is not limited to the case where an extension piece is provided in the distal direction from *all* the inlet openings. Thus, the cannula part distally of the two openings 48 can as a whole be viewed as an extension piece, the latter being a hollow hose with an opening 46). Claims 5 and 8 are considered obvious measures for a person skilled in the art.

4 DEPENDENT CLAIM 4

The combination of features contained in the dependent claim is neither known from the prior art nor suggested in an obvious manner by it. The flexible extension piece in the form of a pigtail permits improved atraumatic support of the cannula on the heart tissue (description, page 7, second paragraph).

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Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

Claim 9 is contradictory to claim 2 and should therefore not be dependent on the latter. If the extension piece has additional openings, then a suction effect, albeit perhaps a small one, exists (see description on page 4, 8th line from bottom), as a result of which the extension piece cannot be regarded as "non-suctioning". The question of whether a "small" effect is "negligible" depends also on the suction effect afforded by the primary inlet openings, which is not defined in claim 9. Moreover, claim 9 does not set any limit on the size of these openings, so that there is not even any indication that this suction effect is indeed small.